

(17) An oath or declaration as set forth in paragraph (b) of this section.

(b) Any oath or declaration submitted in compliance with paragraph (a) of this section must be signed by the owner of record of the patent or its agent, specifically identify the papers and the patent for which an extension is sought and aver that the person signing the oath or declaration:

(1) Is the owner, an official of a corporate owner authorized to obligate the corporation, or a patent attorney or agent authorized to practice before the Patent and Trademark Office and who has general authority from the owner to act on behalf of the owner in patent matters.

(2) Has reviewed and understands the contents of the application being submitted pursuant to this section;

(3) Believes the patent is subject to extension pursuant to § 1.710;

(4) Believes an extension of the length claimed is justified under 35 U.S.C. 156 and the applicable regulations; and

(5) Believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in § 1.720.

(c) If any application for extension of patent term submitted pursuant to this section is held to be informal, applicant may seek to have that holding reviewed by filing a petition with the required fee, as necessary, pursuant to § 1.181, § 1.182 or § 1.183, as appropriate, within such time as may be set in the notice that the application has been held to be informal, or if no time is set, within one month of the date on which the application was held informal. The time periods set forth herein are subject to the provisions of 37 CFR 1.136.

[54 FR 9394, Mar. 24, 1987, as amended at 54 FR 30380, July 20, 1989; 56 FR 65155, Dec. 13, 1991]

**§ 1.741 Filing date of application.**

(a) The filing date of an application for extension of a patent term is the date on which a complete application is received in the Patent and Trademark Office or filed pursuant to the "Certificate of Mailing or Transmission" procedures of 37 CFR 1.8 or "Express Mail" provisions of 37 CFR

1.10. A complete application shall include:

(1) An identification of the approved product;

(2) An identification of each Federal statute under which regulatory review occurred;

(3) An identification of the patent for which an extension is being sought;

(4) An identification of each claim of the patent which claims the approved product or a method of using or manufacturing the approved product;

(5) Sufficient information to enable the Commissioner to determine under 35 U.S.C. 156 subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the length of the regulatory review period; and

(6) A brief description of the activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

(b) If any application submitted pursuant to this section is held to be incomplete, applicant may seek to have this holding reviewed under § 1.181.

[52 FR 9394, Mar. 24, 1987, as amended at 59 FR 54503, Oct. 22, 1993; 61 FR 64028, Dec. 3, 1996]

**§ 1.750 Determination of eligibility for extension of patent term.**

A determination as to whether a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for extension filed in compliance with § 1.740 or § 1.790. This determination may be delegated to appropriate Patent and Trademark Office officials and may be made at any time before the certificate of extension is issued. The Commissioner or other appropriate officials may require from applicant further information or make such independent inquiries as desired before a final determination is made on whether a patent is eligible for extension. In an application for extension filed in compliance with § 1.740,

a notice will be mailed to applicant containing the determination as to the eligibility of the patent for extension and the period of time of the extension, if any. This notice shall constitute the final determination as to the eligibility and any period of extension of the patent. A single request for reconsideration of a final determination may be made if filed by the applicant within such time as may be set in the notice of final determination or, if no time is set, within one month from the date of the final determination. The time periods set forth herein are subject to the provisions of § 1.136.

[60 FR 25618, May 12, 1995]

**§ 1.760 Interim extension of patent term under 35 U.S.C. 156(e)(2).**

An applicant who has filed a formal application for extension in compliance with § 1.740 may request one or more interim extensions for periods of up to one year each pending a final determination on the application pursuant to § 1.750. Any such request should be filed at least three months prior to the expiration date of the patent. The Commissioner may issue interim extensions, without a request by the applicant, for periods of up to one year each until a final determination is made. The patent owner or agent will be notified when an interim extension is granted and notice of the extension will be published in the Official Gazette of the Patent and Trademark Office. The notice will be recorded in the official file of the patent and will be considered as part of the original patent. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be eligible.

[52 FR 9394, Mar. 24, 1987, as amended at 60 FR 25618, May 12, 1995]

**§ 1.765 Duty of disclosure in patent term extension proceedings.**

(a) A duty of candor and good faith toward the Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture rests on the patent owner or its agent, on each attorney or agent who represents the patent owner and

on every other individual who is substantively involved on behalf of the patent owner in a patent term extension proceeding. All such individuals who are aware, or become aware, of material information adverse to the determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding must bring such information to the attention of the Office or the Secretary, as appropriate, in accordance with paragraph (b) of this section, as soon as it is practical to do so after the individual becomes aware of the information. Information is material where there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding.

(b) Disclosures pursuant to this section must be accompanied by a copy of each written document which is being disclosed. The disclosure must be made to the Office or the Secretary, as appropriate, unless the disclosure is material to determinations to be made by both the Office and the Secretary, in which case duplicate copies, certified as such, must be filed in the Office and with the Secretary. Disclosures pursuant to this section may be made to the Office or the Secretary, as appropriate, through an attorney or agent having responsibility on behalf of the patent owner or its agent for the patent term extension proceeding or through a patent owner acting on his or her own behalf. Disclosure to such an attorney, agent or patent owner shall satisfy the duty of any other individual. Such an attorney, agent or patent owner has no duty to transmit information which is not material to the determination of entitlement to the extension sought.

(c) No patent will be determined eligible for extension and no extension will be issued if it is determined that fraud on the Office or the Secretary was practiced or attempted or the duty of disclosure was violated through bad faith or gross negligence in connection with the patent term extension proceeding. If it is established by clear and convincing evidence that any fraud was practiced or attempted on the Office or the Secretary in connection with the